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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/920,295	08/02/2001	Michael Kreindel	KREINDEL=2	3901

1444 7590 10/20/2004

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EXAMINER	
FARAH, AHMED M	

ART UNIT	PAPER NUMBER
3739	

DATE MAILED: 10/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/920,295	KREINDEL, MICHAEL	
	Examiner	Art Unit	
	Ahmed M Farah	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 June 2004*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-11 and 13-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *10* is/are allowed.

6)☒ Claim(s) *1,2,5-9,11 and 13-20* is/are rejected.

7)☒ Claim(s) *21 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/5/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 5-9, 11, and 13-20 are again rejected under 35 U.S.C. 102(b) as being anticipated by Shadduck U.S. Patent No. 6,053,909.

Shadduck discloses a system (see Fig. 7) and method for treating skin of a patient, the system comprising:

a) a surface electrode assembly comprising at least a first pair of a first electrode **40A** and a second electrode **40B**, the first and second electrodes being configured to be applied to the surface of the skin and to apply a voltage to the skin surface (see Fig. 8A and Col. 8, lines 28-36);

b) an electrical meter [comprising a sensor array ***50*** (see Fig 7), impedance-measuring feedback (see Fig. 7 and Col. 13, lines 4-12), temperature measuring-feedback (see Col. 12, line 59 to Col. 13, line 3), and current and voltage-measuring

feedback (see Fig. 7, and Col. 13, lines 18-22)], the meter configured to measure an electrical response of the skin to a voltage applied across the electrodes; and

c) a processor (control system 26) configured to adjust value of a parameter of the radiation based upon a measured electrical response to a voltage applied across the first and second electrodes, and wherein the electrical response of the skin is skin impedance or skin conductivity (see Col. 5, lines 24-34 and Col. 10, lines 22-29).

In reference to claims 1 and 11 of the present application, the first two elements (i.e., *surface radiation assembly configured to irradiate a region on the skin surface with EM radiation; and a surface electrode assembly configured to apply diagnostic voltage to the skin*) are written as if they are directed to two separate elements of the invention. However, Fig. 2; page 4, lines 12-18; and claims 7 and 18 of the applicant's disclosure teach that, in one embodiment, the surface electrode assembly is used to provide the treatment EM radiation as well as the diagnostic voltage.

In one embodiment, Shadduck further teaches that the surface electrode assembly is used to provide for both the diagnostic and treatment energies (see Col. 12, lines 19-23 and lines 28-31). Hence, Shadduck meets the limitations of the

instant claims as recited.

As to claims 2 and 13, the value of the parameters is adjusted in order to control the skin temperature (Col. 12, line 59 to Col. 13, line 3).

As to claims 7 and 18, the first and second electrodes **(40A** and **40B,** respectively) are the source of radiation.

As to claims 5 and 16, the adjusted parameter is selected from the group comprising the irradiation intensity, irradiation frequency, and irradiation duration as presently claimed (see Col. 9, line 57 to Col. 10, line 19).

As to claims 6, 14, 15, and 17, the electromagnetic radiation applied to the skin is in the radio frequency.

Allowable Subject Matter

Claim 10 is allowed. Claims 21 and 22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Although the technique for storing a treatment table into a processor is known in the medical art, the prior art of record do not disclose, teach or suggest an apparatus and methods of use as presently claimed, the apparatus comprising a processor configured to adjust value of a parameter of the radiation based

upon a measured electrical response to a voltage applied across the first and second electrodes, wherein the processor is further configured to store in a memory a table assigning value of one or more parameters of the irradiation to each of one or more non-overlapping impedance ranges, and the value of a parameter of the radiation is adjusted to a value assigned by the table to an impedance measurement; or the step of adjusting a value of a parameter of the radiation to a predetermined value if the impedance is above a predetermined threshold, and adjusting the value of said parameter to 0 if the impedance is below the threshold.

Response to Arguments

Applicant's arguments filed on June 25, 2004 have been fully considered but they are not persuasive. The applicant makes the following remarks/arguments:

A. The applicant states that his invention is directed to a system and method of use, the system defining "a surface radiation assembly for irradiating a region on the surface of the skin with electromagnetic radiation, a surface electrode assembly for applying a voltage to the skin, an electrical meter that measures an electrical response of the skin across the electrodes, and a processor configured to adjust a value of a

parameter of the *electromagnetic radiation* based upon a measured electrical response to a voltage applied across the first and second electrodes."

B. He argues that "Shadduck, discloses an arrangement in which the skin is treated only with RF energy, with electromagnetic radiation being employed only to prime the tissue for the RF treatment." He further argues that, in Shadduck "a parameter of the RF energy, and not of the electromagnetic radiation, is adjusted."

In response to the above statement and arguments, although the first two elements of claims 1 and 11 of the present application *(i.e., the surface radiation assembly and surface electrode assembly)*, are written as if they are directed to two separate and mutually exclusive elements of the invention, the applicant's disclosure teaches differently.

In page 4, lines 12-18 of the instant application, the applicant clearly discloses that "in one embodiment, the voltage applied across the electrodes 125a and b is also used to heat the defect 100." Moreover, the embodiment shown in Fig.2 does not show a separate irradiation device other than the electrodes 125a and b. In addition, Claims 7 and 18 of the instant application further recite that "the first and second electrodes are the source of the radiation."

Hence, in contrary to the applicant's arguments, the surface electrode assembly is used to provide the treatment EM radiation as well as the diagnostic/control voltage. Therefore, the examiner's position is that Shadduck meets the claims as recited.

C. The applicant further argues that the examiner misinterpreted the teachings of Fig.2. He states that "the system illustrated in Figure 2 includes the separate electromagnetic radiation source 115, just like the embodiment of Figure 1."

In a telephone interview with the applicant's attorney, Jay M. Finkelstein (Reg. No. 21,082), on September 2004, the teachings of the embodiment in Fig.2 as described in page 4, lines 12-18 of the instant application were discussed in view of the prior art of record. As a result, the applicant's representative was in agreement and was convinced the similarities between the teachings of the embodiment in Fig. 2 and the prior art of record, *i.e.*, U.S. Patent to Shadduck.

Moreover, the applicant's remarks in page 3, paragraph 1 of the Response filed on June 25, 2004, clearly states that 'in the embodiment of Fig. 2, the electrical response of the skin received by the electrodes 125a and 125b is used to control the voltage applied across said electrodes.' Again, this clearly

teaches that, in the embodiment of Fig. 2, the surface electrode assembly is used to provide both the treatment EM radiation as well as the diagnostic/control voltage.

Note: in this Office Action, the RF current is regarded as the treatment Electromagnetic radiation.

Conclusion

THIS ACTIÓN IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ahmed M Farah whose telephone number is (703) 305-5787. The examiner

can normally be reached on Mon-Thur. 9:30 AM-7:30 PM, and 9:30 AM - 6:30 PM on every other Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M DVorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A. Farah,
Patent Examiner, AU 3739

10/4/2004